

K031877

EXHIBIT 2

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

AUG - 1 2003

Kenneth J. Berk  
80 Oakland Street  
PO Box 780  
Watertown, MA 02472 USA

Telephone: 617-926-6666  
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**DEVICE NAME:** *Embrace™ Wet-Bond Restorative Material*

**PREDICATE DEVICES:**

Pulpdent Embrace™ Pit and Fissure Sealant  
Ivoclar Tetric Flow  
Ivoclar Compoglass Flow  
Kuraray Clear-Fil  
Kerr OptiBond Solo Plus 3

**DESCRIPTION AND INTENDED USE:**

*Embrace™ Wet-Bond Restorative Material* is a hydrophilic, fluoride-releasing, light-cured material recommended for use as a tooth replacement material. Applications of *Embrace™ Wet-Bond Restorative Material* include: Class I, III, IV, and V cavity preparations and as a restorative material for small incipient lesions.

**COMPARISON WITH PREDICATE PRODUCTS:**

*Embrace™ Wet-Bond Restorative Material* is substantially equivalent in design, composition and intended use to the products listed above. Please see Exhibit 4 for the entire comparison.

**SAFETY AND EFFECTIVENESS:**

*Pulpdent Embrace™ Wet-Bond Restorative Material* is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above. The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR 872.3690, 872.3765 or 872.3200. The chemical ingredients used in *Embrace™ Wet-Bond Restorative Material* are used in the predicate products. Though there is no ISO or ANSI/ADA standard applicable to *Embrace™ Wet-Bond Restorative Material*, laboratory testing has shown that *Embrace™ Wet-Bond Restorative Material* is equivalent in physical and mechanical properties to the predicate products.

According to the NIH Technology Assessment Conference on *Effects and Side-Effects of Dental Restorative Materials*: "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio...both composites and glass ionomers are relatively trouble-free. There is no evidence of short-term or long-term risk...There is no suspicion of any problems after virtually billions of procedures in the United States.



AUG - 1 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kenneth J. Berk  
Director  
Pulpdent Corporation  
80 Oakland Street  
Watertown, Massachusetts 02472

Re: K031877

Trade/Device Name: Embrace™ Wet-Bond Restorative Material  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: II  
Product Code: EBF  
Dated: June 13, 2003  
Received: June 24, 2003

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", is written over a horizontal line.

Susan Runner, DDS, MA  
Interim Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510 (k) Number  
(if known)

K031877

Device Name

*Pulpdent Embrace™ Wet-Bond Restorative Material*

### Indications for Use:

*Embrace™ Wet-Bond Restorative Material* is a hydrophilic, fluoride-releasing, light-cured material recommended for use as a tooth replacement material. Applications of *Embrace™ Wet-Bond Restorative Material* include: Class I, III, IV, and V cavity preparations and as a restorative material for small incipient lesions.

Ken Muly for M&R

(Division Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K031877

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

or

Over-The-Counter Use